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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,420	04/16/2004	Kyungyoon Min	F-6097 (9360-0145.01)	9851

69275 7590 03/27/2008

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,420	MIN ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,10-14,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7,10-14 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-6, 10-12, 14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al in view of US 4,985,153 to Kuroda et al.

In the specification and figures, Headley discloses the method substantially as claimed by applicant. With regard to claims 1, 3, 20, and 21, Headley discloses a method for collecting and separating whole blood comprising the steps of providing a disposable blood separation set (see FIG 1) that mounts on a reusable separator and control unit 20 (see column 3, lines 15-25). The disposable set comprises a cannula 10 or fluid flow path for communicating with a source, and a processing chamber 21.

Headley discloses the steps known in the prior art of connecting cannula or port 10 to a donor, flowing fluid from the donor to an initial container 12 with anticoagulant, disconnecting the patient from the set before blood is processed, mounting the set in a centrifuge, processing the blood through in processing chamber 13, processing the collected blood to separate into the desired components, and disconnecting the donor from the system before the separation process is complete (see column 1, lines 25-60).

Headley discloses the steps of flowing fluid from a donor via cannula 10 directly into a processing chamber/rotor 21, processing the collected blood in the rotor to separate it into desired components, and disconnecting the donor from the system after processing begins, but before the plasma is urged from the rotor, so before the processing ends (see column 4, lines 1-10).

With regard to applicant's claimed step of mounting the disposable circuit onto the controller, Headley discloses that the disposable set is mounted in the reusable assembly prior to connecting the set to a patient. However, the language of the claim does not set forth a specific order of the steps performed in the method. It is improper to read a specific order of steps into method claims where the language of the method claims did not impose a specific order on the steps and the specification did not require a particular order (see MPEP 2111.01(II)). Applicant's specification, at paragraphs 0021, indicates that the disposable set may be mounted on the reusable device before or after the set is connected to the donor. As such, since Headley discloses all the steps in the claimed method and applicant does not specify an order of the claimed steps, it would have been obvious to rearrange the steps disclosed by Headley to arrive at the claimed method.

Headley fails to disclose the step of flowing the collected donor blood into an initial collection chamber before passing it to the processing chamber. However, such initial collection containers are well-known in the art, as disclosed by Headley and Kuroda. Kuroda discloses a method and apparatus for collecting and processing blood comprising a blood collector means 1 that may comprise a cannula 16, connector 18,

and blood collection bag 17 with anticoagulant 18. Blood is collected from the patient via cannula 16, mixed with anticoagulant in collection bag 17, and passed to the remainder of the processing apparatus, including processing chamber 3, via connector 8 (see FIG 6, column 13, lines 8-48).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of passing the collected blood through an initial container on its way to the processing chamber, as disclosed by Kuroda, to the blood collection and processing method disclosed by Headley in order to provide a chamber for thorough mixing of blood with anticoagulant, as suggested by Kuroda.

With regard to claims 4-6, 14, Headley discloses that the rotor or collection chamber in the disclosed embodiment has a variable volume (see column 3, lines 15-34). It has been held that where the general conditions of a claim are disclosed in the prior art, it is within the skill of a worker in the art to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). Since Headley specifically discloses that the volume of blood collected may vary from patient to patient, it is the position of the examiner that the amount of whole blood collected is a result-effective variable, the optimization of which is within the skill of a worker in the art.

With regard to claim 10, Headley discloses that the blood source is a “donor,” (see column 1, lines 25-30), which is well-known in the art to comprise a human donor (see US 5,906,589 to Gordon et al that discloses apheresis blood supply as typically a human donor/patient at column 3, lines 55-60).

With regard to claims 11 and 12, Headley discloses that the system and method may be use to separate all the collected blood into constituent components simultaneously (see column 4, lines 20-30) or sequentially, wherein plasma is removed from the blood before RBC separation (see column 4, lines 13-16).

3. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al in view of US 4,985,153 to Kuroda et al, further in view of US 6,743,192 to Sakota et al.

In the specification and figures, Headley and Kuroda disclose the method substantially as claimed by applicant (see rejection above) with the exception of providing additional whole blood bags and pooling whole blood before processing. Sakota discloses a blood apheresis apparatus and method comprising a disposable fluid circuit with a phlebotomy needle 24 that connects to a donor. The phlebotomy needle may be replaced with a whole blood bag in case whole blood is to be pooled and then supplied to the apheresis system (see column 6, lines 55-65) in order to increase the amount of whole blood processed in a single round of apheresis (see column 2, line 56 to column 3, line 37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add the additional containers and pooling whole blood as disclosed by Sakota in the process disclosed by Headley in order to increase the volume of whole blood processed, as taught by Sakota.

Response to Arguments

4. Applicant's amendment and arguments filed 25 January 2008 have been entered and considered.

5. Applicant's cancellation of claims 2 and 8-9 have rendered moot the 35 USC § 112 rejections presented in the Office action mailed 26 October 2007. Accordingly, the rejections have been withdrawn.

6. Applicant's arguments have been fully considered but they are not persuasive.

7. Applicant argues that the Headley reference describes only systems wherein a donor is disconnected from the system before processing begins or after processing ends.

Specifically, applicant notes that the apparatus depicted in FIG 1 and the accompanying text discloses a system in which blood is collected and the donor is disconnected from the collection apparatus before processing begins (Headley column 1, lines 33-39, as pointed out by applicant). However, the Examiner notes that FIG 1 is labeled "Prior Art" and Headley discloses a system that is "a typical disposable bag set that is used in the **prior art** to process blood" (Headley column 1, lines 26-27, emphasis added). Accordingly, Headley is not disclosing such an embodiment as a part of the disclosed invention.

To the contrary, Headley specifically discloses an apparatus and method in which blood is collected from the patient, moved into the rotor where components are separated (which comprises the processing step claimed by applicant), and then the patient is disconnected from the separation apparatus before the separated

components are urged from the rotor (see column 2, lines 25-35, column 4, lines 5-8) and before all the fluid in the circuit is processed in the processing chamber ("the second component…is urged from the rotor through the filter" thus separating red blood cells and white cells, which Headley calls comprises a processing step—column 2, lines 37-39, 51-52).

. As such, Headley discloses an embodiment in which the donor is disconnected after processing or separation in the rotor begins, but before all the blood in the fluid circuit is processed in the processing chamber (since Headley specifically discloses that the separated components undergo further processing after donor disconnection, see column 2, lines 36-42).

Applicant notes that Headley discloses a further preferred embodiment in which the donor is disconnected from the apparatus before the rotor is spun (see column 4, lines 9-12). However, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. See MPEP § 2123(I). In the instant case, Headley discloses that the latter embodiment is more preferred than the embodiment in which the donor is disconnected from the machine during processing. However, the fact that Headley prefers the second embodiment to the first does not vitiate the fact that the first embodiment is disclosed.

Applicant argues that rejecting the claims over the two disclosed embodiments requires improperly treating the embodiments as mutually exclusive. The Examiner is unsure what Applicant is intending to argue. Taken as a whole, the reference

reasonably suggests two embodiments of patient disconnection—before processing begins, as disclosed in column 4, lines 9-12, or after processing begins ("needle is removed from the donor before any of the components are urged from the rotor"—column 2, lines 34-35) and before all the fluid in the circuit is processed in the processing chamber ("the second component…is urged from the rotor through the filter" thus separating red blood cells and white cells, which Headley calls a processing step—column 2, lines 37-39, 51-52). Accordingly, Headley suggests the steps claimed by applicant, and the instantly claimed invention is unpatentable over the prior art.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
18 March 2008